

PSJ15 Exh 2



A Manufacturers Perspective: Addressing The Challenges of Opioid Diversion

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Mallinckrodt Pharmaceuticals

Est 1867



1867
Establishes G.
Mallinckrodt
and Company



1898
Began producing
morphine and
codeine for pain
relief



1940's
Increased
morphine
production for war
effort



2010
Expand pain
franchise with
three product
launches



1995
Launched first
generic
product



1971
Began
production of
acetaminophen



2013
Mallinckrodt
separates from
Covidien



2015
Mallinckrodt
expands into the
autoimmune – rare
disease space



Mallinckrodt: Managing Complexity. Improving Lives.

- Global specialty biopharmaceutical company focused on pain management, spasticity disorders and autoimmune and rare diseases
- More than 5,500 employees operating in 65 countries worldwide
- Strong market positions:
 - Vertically integrated manufacturer
 - Pharmaceutical formulation expertise
 - Global regulatory capabilities



Mallinckrodt Provides Expertise

- Importer of Raw Opium
- Bulk API Manufacturer
- Generic Dosage Manufacturer
- Branded Pharmaceuticals
- Addiction Treatment Manufacturer



Regulatory Compliance Interfaces

- U.S. Food and Drug Administration
- U.S. Occupational Safety and Health Administration
- U.S. Environmental Protection Agency
- U.S. Drug Enforcement Agency
- U.S. Bureau of Alcohol Tobacco & Firearms
- U.S. Department of Homeland Security
- Missouri Department of Natural Resources
- Missouri Board of Pharmacy



Engaged in Appropriate Use

For nearly 150 years, Mallinckrodt has held the values of quality, integrity and service



Provide comprehensive, effective treatments for people with pain



Improve the integration of federal and state Prescription Drug Monitoring Programs (PDMP)



Improve stakeholder education



Enhance drug take-back



Support the development of abuse-deterrent technologies



Develop and share best practices in anti-diversion methodologies



Prescription Drug Abuse: National Concern

Teen Use

Among teenagers and young adults treated in emergency rooms for any reason, 10.4% admit they have misused a prescription painkiller at least once in the last year¹

Overdose

The number of women dying from overdoses of opioid painkillers increased more than 400 percent between 1999 and 2010²

Heroin Use

There is growing evidence to suggest a relationship between increased non-medical use of opioid analgesics and heroin abuse in the United States³

1. The Journal of Pediatrics, October 21, 2013
2. Centers for Drug Control & Prevention, July 2, 2013
3. *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the US. Center for behavioral Health Statistics and Quality Data Review. SAMHSA (2013)*



Our View of Diversion and Abuse

- A Complex Problem
 - Millions of patients face acute and chronic pain every day
 - No one policy initiative or single program will bring a solution
- Our Commitment
 - Seek to provide safe and effective medications for treatment of patients with chronic and acute pain
 - Work with policy makers, law enforcement and stakeholders to address the complex issues of opioid diversion and abuse
- A Multi-Dimensional Approach for all Stakeholders
 - Education
 - Tracking and monitoring
 - Abuse-Deterrent Technology
 - Safe Disposal
 - Enforcement



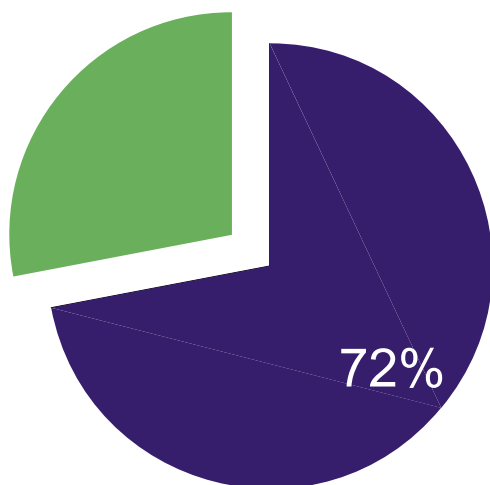
PDMPs: Achieving Full Potential

- PDMPs support prescribers and help prevent abuse by providing timely data for the treatment of patients
- Help identify illicit activities such as “doctor shopping”
- Shorten the time needed to conduct investigations and lower overall abuse and diversion rates.
- Opportunities for Improvement:
 - Improve the integration of federal and state programs
 - Increase cooperation among states
 - Uniform standards should be developed for data reporting and transparency to prescribers and pharmacies
 - Medicare and Medicaid programs and other payers should offer a financial incentive to prescribers and pharmacies that consistently use PDMP data
- Mallinckrodt supports, and has provided funding for the Missouri PDMP NOW Coalition

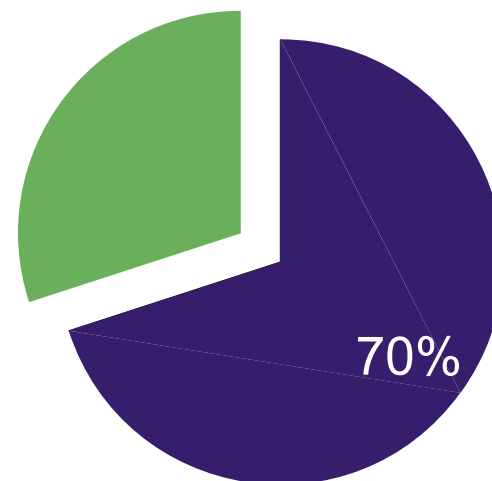


Stopping Diversion Begins At Home

An important first step is disposing of unused opioids



72% of patients that were prescribed opioids reported having leftover amounts¹



More than 70% of people who abused prescription pain relievers got them from friends or relatives²

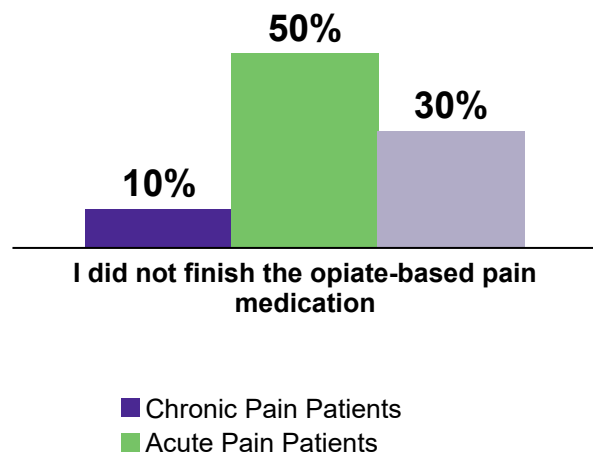
1. *Morbidity and Mortality Weekly report* Vol 59, No. 6, Center for Disease Control and Prevention Feb 19, 2010

2. 2009 *National Survey on Drug Use and Health (NSDUH): National Findings*, SAMHSA (2010).

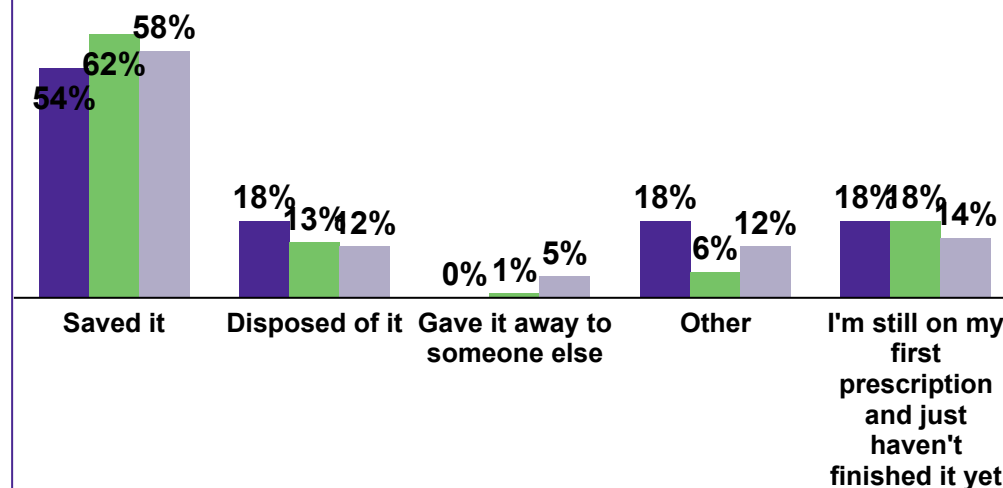


Unused Opioids Often Saved for Future Use

When it comes to your opiate-based pain medication, have you done any of the following?



You indicated that you did not finish your opiate-based pain medication. What did you do with the extra medication?



"Prescribers, Patients and Pain: New Research Highlights Opportunities for Better Prescriber-Patient Communication" Webinar, Presented April 29, 2015; Partnership for Drug-Free Kids; American Cancer Society; American Academy of Pain Management; Mallinckrodt Pharmaceuticals; n = 705 chronic/acute patients



Home Diversion of Unused Opioids is Broad



Family (grandchildren; teenagers)

Babysitters

Delivery people

Maintenance/home improvement workers

House hunters (if house is for sale)

Neighbors

Friends



Drug Disposal; Take Back Programs

- Community Take-Back Programs
 - Mallinckrodt supports the use of drug drop boxes and take-back programs, but challenges exists:
 - Take-back programs are infrequent; not top of mind
 - Requires coordination with law enforcement and volunteers
 - Cost associated with managing event and destruction of medications
 - Housebound /elderly may not be able to actively participate
 - Collection of controlled substances may be marginal*
- Home Disposal
 - Flush the prescription down the drain (i.e. opioids, as recommended by the FDA)
 - Mix the drug with an undesirable substance (e.g., kitty litter) and throw the mixture in the trash

* Wake Forest, TN controlled substances collection = 1%; Lessons learned from Rx Disposal; presented at the National Rx Drug Abuse Summit, Atlanta, GA, Wednesday, April 8, 2015



Mallinckrodt and Opioid Disposal Initiative

- Mallinckrodt distributes medication inactivation pouches*
 - Contains activated carbon
 - When combined with water neutralizes active ingredients
 - Active pharmaceutical ingredients cannot be extracted
- Safe, convenient, environmentally friendly way for disposal
- Minimizes potential for diversion or accidental exposure



* Manufactured by Verde Environmental Technologies; Deterra® LP Medication Inactivation Pouches



Anti-Diversion and the Supply Chain

- A comprehensive anti-diversion program is an important component of addressing opioid diversion
- Our goal is to strive for 'ideal' supply chain
- DEA requirements:

21 CFR 1301.74(b)

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Mallinckrodt's Industry-Leading Anti-Diversion Program



- We have a thorough process of customer due diligence, including verifying DEA registrations and customer questionnaires
- Verify each DEA 222 form for accuracy
- Implement a two-tiered system of algorithms according to type and volume of product orders
- Automatic flag (hold) on new customers and/or new orders
- More restrictive than that noted by the DEA



Preventing Diversion Through Suspicious Order Monitoring (SOM)

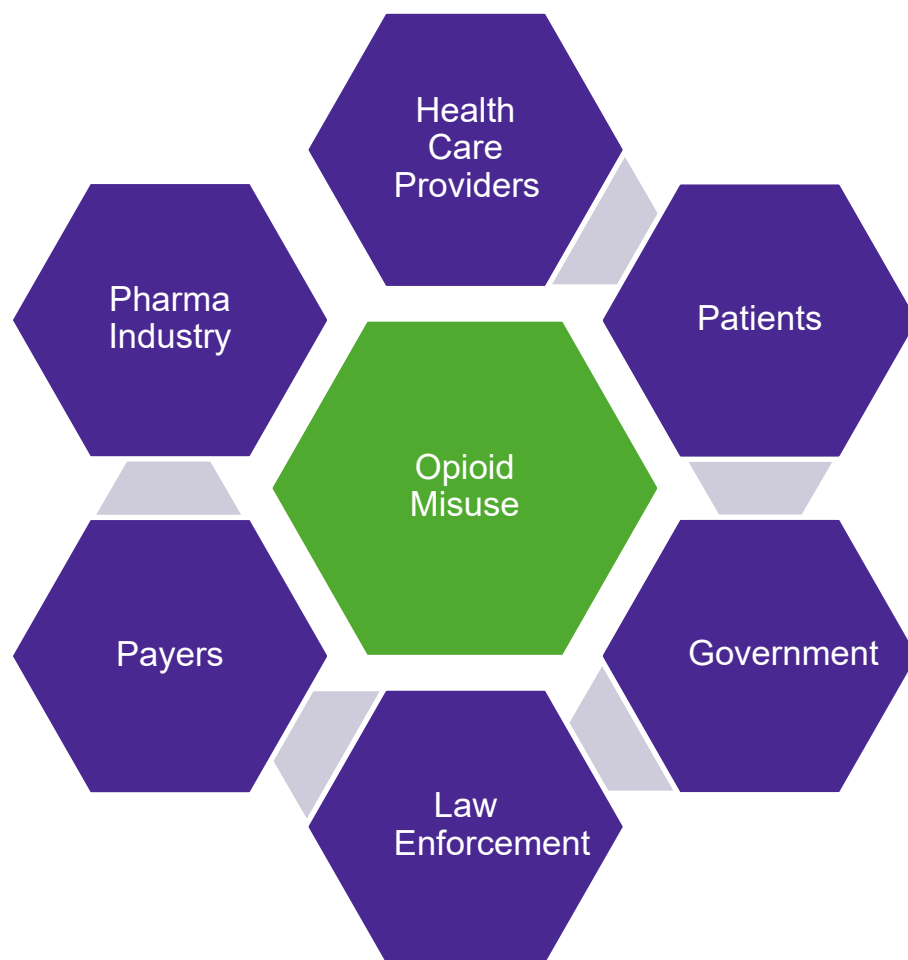
- Industry leading authority, often providing advice to other opioid manufacturers
- Proprietary (patent pending) monitoring of customer orders to detect unusual pattern, size, frequency orders are investigated prior to release
- Pharmacy ordering red flags include:
 - Volume of certain controlled substances relative to pharmacy
 - Business model
 - Location
 - Percentage of controlled substances sold vs. non-controlled
 - Percentage of cash business
 - High-volume controlled substances prescribers



Chargeback Restricting Pharmacies

- When a pharmacy represents too great a risk for diversion, we “chargeback restrict” the pharmacy
 - Contractual discount by manufacturers to pharmacies honored by distributors
- Notify all distributors we will not pay chargebacks on their sales of our products to the pharmacy
- DEA is notified as well
- A significant financial disincentive for distributors
- Pharmacy can still buy other manufacturers’ products

Addressing Opioid Misuse Requires Broad Stakeholder Engagement



‘Pain represents a national challenge. A cultural transformation is necessary to better prevent, assess, treat and understand pain of all types. Government agencies, healthcare providers, healthcare professional associations, educators, and public and private funders of health care should take the lead in this transformation.’

Institute of Medicine
Relieving Pain in America,
June 2011



Anti-Diversion Industry Working Group

- Membership:

- Mallinckrodt engaged manufacturers and large distributors of generic hydrocodone/acetaminophen and oxycodone IR products

- Mission:

- Address diversion and abuse through stakeholder collaboration
- Work together to multiply the impact of each company's efforts
- Work with law enforcement and engage with regulatory agencies
- Better educate patients, prescribers and pharmacists
- Promote innovative anti-diversion solutions within the pharmaceutical supply chain

- Progress:

- Collaborative with National Association Boards of Pharmacy: Red 7/29/2019
Flag Video



Mallinckrodt: Partner with Law Enforcement

- Motto: “How Can We Help?”
- John Gillies, Vice President of Global Security
- Affidavits on Mallinckrodt products
- Expert witness for the prosecution at criminal trials



Law Enforcement Collaboration: Placebos

- Mallinckrodt offers at no cost placebos of our Oxycodone 30mg IR and Hydrocodone/Acetaminophen 10/325 tablets
- Used by law enforcement in buy/busts and other sting operations
- No Oxycodone, nor Hydrocodone/Acetaminophen in them – less paperwork and more flexibility
- Provided Hydrocodone 10/325 placebos to 11 task forces in 8 states totaling 10,500 placebos
- Provided Oxycodone 30 placebos to 44 task forces in 22 states totaling 270,250 placebos



Law Enforcement Collaboration: GPS Tracking

- Mallinckrodt partners with two companies to place GPS tracking devices in Mallinckrodt trade bottles labeled as Oxycodone and Hydrocodone
- Bottles blend in with other retail pharmacy stock inventory
- GPS embedded bottle placed in carrier cradle, that when removed during robbery, activates tracking device
- Alert sent to tracking center, which is manned 24/7, and authorities are notified

Research Reveals ‘Disconnects’ Between Prescribers and Patients Regarding Safe Use



Addressing prescription opioid diversion also requires support of both the prescribing physician and patient

Survey Methodology

	Opiate Providers	Pain Patients
Field Dates	December 30 th 2014 - January 3 rd 2015	December 30 th 2014 - January 13 th 2015
Sample Size	N=360 physicians who have prescribed opiates in the past 30 days	N=705 adults (18+) who have filled an opiate prescription in the past 60 days
Sample Design	N=360 Doctors <ul style="list-style-type: none"> • N=205 Primary Care Physicians • N=51 Pain Management Specialists • N=53 Oncologists • N=51 Surgeons 	N=705 Pain Patients <ul style="list-style-type: none"> • N=401 Chronic Pain Patients • N=304 Acute Paint Patients • N=145 Cancer-Related Pain Patients (acute or chronic)
Margin of Error	Margin of error at the 95% CL: <ul style="list-style-type: none"> • ± 6.8% for Primary Care Physicians • ± 13.8% for Pain Management Specialists, Oncologists, and Surgeons 	Margin of error at the 95% CL: <ul style="list-style-type: none"> • ± 4.8% for Chronic Pain Patients • ± 5.6% for Acute Pain Patients • ± 8.1% for Cancer-Related Pain Patients

“Prescribers, Patients and Pain: New Research Highlights Opportunities for Better Prescriber-Patient Communication” Webinar, Presented April 29, 2015; Partnership for Drug-Free Kids; American Cancer Society; American Academy of Pain Management; Mallinckrodt Pharmaceuticals



Key Findings – Disconnects in Patient Behavior¹

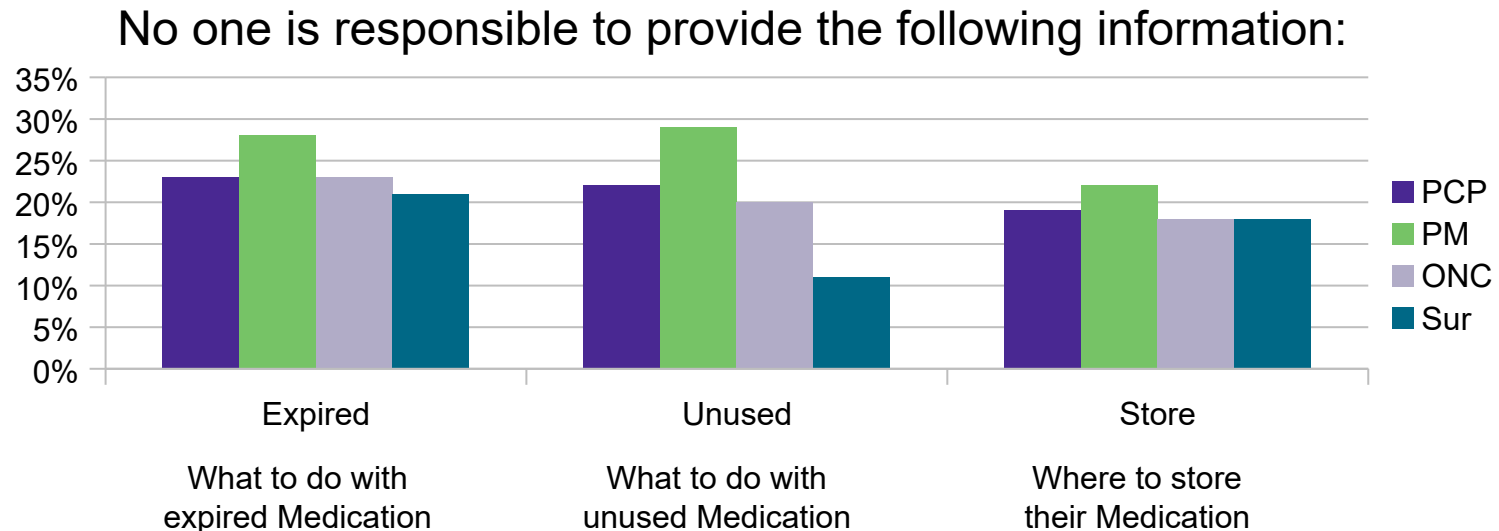
- Only 11 percent of chronic pain patients and 13 percent of acute pain patients say they are concerned with someone else in their household accessing their medications
- Most patients reported they did not receive information on where to store medication (51 percent of chronic pain patients; 58 percent of acute pain patients);
- Or what to do with expired medication (57 percent of chronic pain patients and 60 percent of acute pain patients)

1. Prescribers, Patients and Pain: New Research Highlights Opportunities for Better Prescriber-Patient Communication” Webinar, Presented April 29, 2015; Partnership for Drug-Free Kids; American Cancer Society; American Academy of Pain Management; Mallinckrodt Pharmaceuticals



Key Findings – Disconnects in Physician Behavior¹

- Approximately 1 in 5 prescribers said they “always” give their patients information on how to store and dispose of their medications, including information on where to store medication
- Many physicians believe that proper storage and disposal is not a concern:



1. Prescribers, Patients and Pain: New Research Highlights Opportunities for Better Prescriber-Patient Communication” Webinar, Presented April 29, 2015; Partnership for Drug-Free Kids; American Cancer Society; American Academy of Pain Management; Mallinckrodt Pharmaceuticals



Implications of a Safe Use; Storage & Disposal

- Research reveals that there is a lack of concern from both health care providers and patients regarding the potential repercussions of prescription drug diversion, which patients seldom seek out and health care providers unlikely to provide
- If left unaddressed, these pain-related communication disconnects may leave patients uninformed about the risks of misusing or abusing prescription drugs



Addressing the Societal Burden of Opioid Misuse Requires A Balanced Approach

Ensure people with pain have access to available treatment options



Share responsibility among stakeholders to assure proper use, disposal and protection against diversion (of opioids)

‘The public health outcome is at its maximum when the optimum is reached between maximizing access for rational medical use and minimizing hazardous or harmful use’

*Ensuring Availability of Controlled Medications for the Relief of Pain and Preventing Diversion and Abuse;
United Nations Office on Drugs and Crime*




ALLIANCE FOR


Balanced Pain
Management




Goals of the Alliance



Ensure people with or affected by pain have access to appropriate, integrated pain management




Drive patient safety: Prescribe, dispense, take, store and dispose of prescription medications with an aim to reduce abuse, misuse and diversion.




Create tools and messaging for its members to educate their constituents and the public about integrated pain management strategies and responsible use of medicine.


How is the Alliance Different?



Focus on societal burden of ensuring access and safe use (not policy/legislative agenda)



Focus is limited to 2-3 actionable initiatives



Members agree to speak with one voice to magnify impact and pull through messaging with their respective constituents



Over 25 Organizations Have Come Together With A Shared Mission

Alliance for Patient Access

American Academy of
Pain Management

American Cancer Society

American Chronic Pain
Association

American Pain Society

American Society for Pain
Management Nursing

Caregiver Action Network

Community Anti-Drug
Coalitions of America

Easter Seals

Leukemia & Lymphoma
Society

Mallinckrodt
Pharmaceuticals

Men's Health Network

National Alliance for
Caregiving

National Alliance for State
Pharmacy Associations

National Association of
Chain Drug Stores

National Association of Drug
Diversion Investigators

National Black Nurses
Association

National Minority
Quality Forum

National Patient Safety
Foundation

Otsuka America
Pharmaceuticals

Partnership for Drug-
Free Kids

The Gerontological
Society of America

US Pain Foundation

Verde Environmental
Technologies

Veterans Health Council &
Vietnam Veterans of
America

Alliance for Balanced Pain Management Working Groups



Workgroup #1: Access

Patient survey to determine frequency of denial of access, potential issues associated with denial of access, and what the patient did as a result



Workgroup #2: Patient Safety

Patient checklist to self identify if they are inadvertently putting themselves or their family at risk when an opioid is prescribed



Next Steps: Understanding Behavior to Dispose of Unused Prescription Medications

- Mallinckrodt Pharmaceuticals is engaging the Community Anti Drug Coalitions of America (CADCA) to conduct a pilot study in the State of Florida to understand what ultimately influence a patient's behavior to dispose of unused medications, namely:
 - Patient/Family Safety (Accidental exposure)
 - Community (Risk of diversion)
 - Environment (Contamination of ground water)
- Results will be published and presented at the National CADCA Conference
- Research will be conducted in collaboration with a to-be-named Florida based environmental organization
- Mallinckrodt will provide 40,000 biodegradable medication inactivation pouches for the study



Mallinckrodt's Commitment to Safe Use

- Partner with law enforcement and industry to minimize misuse and diversion
 - Suspicious Order Monitoring Program
 - Red Flags video
 - Placebo product
 - Tracking devices
 - Drug drop boxes
- Engage an alliance of industry partners to speak with one voice
- Identify opportunities for improvement to address the importance of safe use, storage and disposal, and provide the necessary tools and messages to act
- Law enforcement and industry – a critically important partnership



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Thank You